510(K) SUMMARY

SEP - 5 2007

510(K) Number K071966

5.1 Applicant's Name:
INSIGHTEC, LTD.
5 Nahum Heth st.
Tirat Carmel, 39120
ISRAEL

5.2 Contact Person:
Ori Lubin
InSightec Ltd
Regulatory Affairs Manager
Nahum Heth St.
Tirat Carmel,
Israel, 39120
Tel.: 001-972-544-881-399
Email: Oril@InSightec.com

5.3 Date Prepared:
July 2007

5.4 Trade Name:
MRgFUS Pelvic Coil

5.5 Classification Name:
Magnetic Resonance Diagnostic Device

5.6 Medical Specialty:
Radiology

5.7 Product Code:
MOS

5.8 Device Class:
II

5.9 Regulation Number:
CFR 892.1000

5.10 Panel:
Radiology

5.11 Predicate Device:
Pelvic Array Coil (USA Instruments, Inc.), K033753.

5.12 Performance Standards:
IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995).
IEC 60601-2-33 (2002-05); Medical Electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
UL 94; Tests for Flammability of Plastic Materials for parts in Devices and Appliance
NEMA: MS 6 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images
FDA Guidance for Diagnosis Submission of Premarket Notification for Magnetic Resonance Diagnostic Devices, FDA, CDRH

5.13 Intended Use / Indication for Use:
The Pelvic Array Coil is a receive only phased array RF coil used for obtaining diagnostic images of the pelvis, including the hips, in magnetic resonance imaging systems. The Pelvic Array Coil is designed for use with the GE 1.5T MRI systems manufactured by GE Medical Systems.
The Pelvic Array Coil can be used in conjunction with the InSightec Focused UltraSound (FUS) treatment.

5.14 Device Description:
The MRgFUS Pelvic Array Coil is a receive-only, quadrature phased array RF coil, used for obtaining diagnostic MR images of the pelvis, including the hips. The elements and associated circuitry are enclosed in both rigid and semi-flexible housing that is fire rated and has a high impact and tensile strength.

5.15 Substantial Equivalence:

The MRgFUS pelvic array Coil manufactured by InSightec is equivalent to the pelvic array coil manufactured by USAI for InSightec

The MRgFUS Coil and its predicate device also share common technological characteristics and principles of operations. Specifically, similar to its predicate, it employs the following characteristics:

- Receive-only coil.
- A dual elements coil as a basic structure component.
- Comparable dimensions and weight.
- Compatibility with 1.5 T GE MRI Systems.
- Active and passive RF Decoupling circuits.
- Employ hydrogen nuclei excitation for the imaging of the scanned organ.
- Operation in conjunction with the InSightec Focused UltraSound (FUS) treatment employing MR thermometry to monitor temperature.
- Optimal Signal to Noise Ratio (SNR) and coverage and high-resolution imaging

In addition, the MRgFUS Coil was tested to verify that it meets its specifications and conforms to the relevant recognized standards, to ensure that any minor difference between the coil and its predicate does not raise any new questions of safety and effectiveness.

Based on the safety and performance testing results, and the analysis of similarities and differences summarized above, InSightec Ltd. believes that the MRgFUS Coil is substantially equivalent to its predicate device, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 5 2007

Mr. Nadir Alikacem
Pole Manager
InSightec-TxSonics, Inc.
2777 Stemmons Frwy, Suite 940
DALLAS TX 75204

Re: K071966
Trade/Device Name: MRgFUS Pelvic Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 8, 2007
Received: July 16, 2007

Dear Mr. Alikacem:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071966

Device Name: MRgFUS Pelvic Coil

Indications For Use:

The Pelvic Array Coil is a receive only phased array RF coil used for obtaining diagnostic images of the pelvis, including the hips, in magnetic resonance imaging systems. The Pelvic Array Coil is designed for use with the GE 1.5T MRI systems manufactured by GE Medical Systems.
The Pelvic Array Coil can be used in conjunction with the InSightec Focused UltraSound (FUS) treatment.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071966